
CIRM Creates First of its Kind Center to Accelerate Stem Cell Development

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Oakland, CA – How do you overcome obstacles slowing the progress of even the most promising stem cell therapies? Simple, you create a new, innovative center that has the skill, experience and expertise to help researchers move their work out of the lab and into clinical trials in people.

The governing Board of CIRM, the California Institute for Regenerative Medicine, today approved investing \$15 million in a partnership with Quintiles Transnational Inc. to create a stem cell Accelerating Center. This unique institution will provide researchers with the support and management services they need to increase the likelihood their clinical trials will succeed.

CIRM projects run through the Accelerating Center will be given a discount on services. CIRM expects to receive a \$22.5 million, or 50 percent, return on its \$15 million investment.

"Many scientists are brilliant researchers but have little experience or expertise in navigating the regulatory process; this Accelerating Center means they don't have to develop those skills, we provide them for them," says C. Randal Mills, Ph.D., President and CEO of CIRM. "This partnership with Quintiles means that CIRM projects will not only be accelerated, but that CIRM will also realize a reasonable financial return on this investment."

Quintiles has a lot of experience and expertise in this area. It is a Fortune 500 company and the world's largest provider of biopharmaceutical development and commercial outsourcing services.

The Accelerating Center will provide key core services:

- Regulatory support and management services
- Clinical trial operations and management services
- Data management, biostatistical and analytical services

The Accelerating Center is one of three new Infrastructure Programs under CIRM 2.0. This system designed to help provide researchers with the services and support they need to be able to apply for and run a successful clinical trial. The other components are a Translating Center, which will focus on pre-clinical work and shorten the amount of time it takes to move research into a clinical trial, and the CIRM Alpha Stem Cell Clinic Network, a series of clinics that specialize in conducting high quality trials.

The CIRM Board also approved investing \$4.24 million to develop a treatment for vision loss caused by damage to the cornea.

The cornea is the transparent layer that forms the front of the eye and it plays an important role in focusing our vision. A healthy cornea relies on its store of limbal epithelial stem cells to repair any damage. But when those cells are damaged the cornea is unable to repair injuries resulting in blurred vision or even blindness.

UCLA researcher Sophie Deng plans to develop a method of using the patient's own limbal stem cells to repair the damage, removing them from the eye, expanding their numbers in the lab and then transplanting them back into the eye to create a healthy cornea. Deng hopes to be ready to apply to the FDA for approval for a clinical trial in two years.

"Losing your sight can have such a profound impact on a person's life. Imagine not being able to see the faces of those you love," says Jonathan Thomas, Ph.D., JD, Chair of the CIRM Board. "We already have two projects targeting blindness in clinical trials, and hope Dr. Deng's work will make it three. The more shots on goal we can take in addressing any problem the more likely we are to be successful."

At CIRM, we never forget that we were created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and act with a sense of urgency to succeed in that mission.

To meet this challenge, our team of highly trained and experienced professionals actively partners with both academia and industry in a hands-on, entrepreneurial environment to fast track the development of today's most promising stem cell technologies.

With \$3 billion in funding and approximately 300 active stem cell programs in our portfolio, CIRM is the world's largest institution dedicated to helping people by bringing the future of cellular medicine closer to reality.

For more information, go to www.cirm.ca.gov.

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